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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,277	08/19/2003	Jean M. Gudas	ABGENIX.091A	6274

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EXAMINER

TUNGATURTHI, PARITHOSH K

ART UNIT PAPER NUMBER

1643

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,277	GUDAS ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 41 and 44 in part and 3, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:2 and the light chain amino acid having a sequence of SEQ ID NO:4, classified in class 530, subclass 387.1+.
 - II. Claims 1, 2, 41 and 44 in part and 4, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:6 and the light chain amino acid having a sequence of SEQ ID NO:8, classified in class 530, subclass 387.1+.
 - III. Claims 1, 2, 41 and 44 in part and 5, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:10 and the light chain amino acid having a sequence of SEQ ID NO:12, classified in class 530; subclass 387.1+.
 - IV. Claims 1, 2, 41 and 44 in part and 6, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:14 and the light chain amino acid having a sequence of SEQ ID NO:16, classified in class 530, subclass 387.1+.
 - V. Claims 1, 2, 41 and 44 in part and 7, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ

ID NO:18 and the light chain amino acid having a sequence of SEQ ID NO:20, classified in class 530, subclass 387.1+.

- VI. Claims 1, 2, 41 and 44 in part and 8, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:22 and the light chain amino acid having a sequence of SEQ ID NO:24, classified in class 530, subclass 387.1+.
- VII. Claims 1, 2, 41 and 44 in part and 9, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:26 and the light chain amino acid having a sequence of SEQ ID NO:28, classified in class 530, subclass 387.1+.
- VIII. Claims 1, 2, 41 and 44 in part and 10, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:30 and the light chain amino acid having a sequence of SEQ ID NO:32, classified in class 530, subclass 387.1+.
- IX. Claims 1, 2, 41 and 44 in part and 11, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:34 and the light chain amino acid having a sequence of SEQ ID NO:36, classified in class 530, subclass 387.1+.
- X. Claims 1, 2, 41 and 44 in part and 12, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:38 and the light chain amino acid having a sequence of SEQ ID NO:40, classified in class 530, subclass 387.1+.

- XI. Claims 1, 2, 41 and 44 in part and 13, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:42 and the light chain amino acid having a sequence of SEQ ID NO:44, classified in class 530, subclass 387.1+.
- XII. Claims 1, 2, 41 and 44 in part and 14, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:46 and the light chain amino acid having a sequence of SEQ ID NO:48, classified in class 530, subclass 387.1+.
- XII. Claims 1, 2, 41 and 44 in part and 15, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:50 and the light chain amino acid having a sequence of SEQ ID NO:52, classified in class 530, subclass 387.1+.
- XIII. Claims 1, 2, 41 and 44 in part and 16, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:54 and the light chain amino acid having a sequence of SEQ ID NO:56, classified in class 530, subclass 387.1+.
- XIV. Claims 1, 2, 41 and 44 in part and 17, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:58 and the light chain amino acid having a sequence of SEQ ID NO:60, classified in class 530, subclass 387.1+.
- XV. Claims 1, 2, 41 and 44 in part and 18, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ

ID NO:62 and the light chain amino acid having a sequence of SEQ ID NO:64, classified in class 530, subclass 387.1+.

- XVI. Claims 1, 2, 41 and 44 in part and 19, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:66 and the light chain amino acid having a sequence of SEQ ID NO:68, classified in class 530, subclass 387.1+.
- XVII. Claims 1, 2, 41 and 44 in part and 20, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:70 and the light chain amino acid having a sequence of SEQ ID NO:72, classified in class 530, subclass 387.1+.
- XVIII. Claims 1, 2, 41 and 44 in part and 21, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:74 and the light chain amino acid having a sequence of SEQ ID NO:76, classified in class 530, subclass 387.1+.
- XIX. Claims 1, 2, 41 and 44 in part and 22, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:78 and the light chain amino acid having a sequence of SEQ ID NO:80, classified in class 530, subclass 387.1+.
- XX. Claims 1, 2, 41 and 44 in part and 23, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:82 and the light chain amino acid having a sequence of SEQ ID NO:84, classified in class 530, subclass 387.1+.

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- XXI. Claims 1, 2, 41 and 44 in part and 24, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:86 and the light chain amino acid having a sequence of SEQ ID NO:88, classified in class 530, subclass 387.1+.
- XXII. Claims 1, 2, 41 and 44 in part and 25, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:90 and the light chain amino acid having a sequence of SEQ ID NO:92, classified in class 530, subclass 387.1+.
- XXIII. Claims 1, 2, 41 and 44 in part and 26, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:94 and the light chain amino acid having a sequence of SEQ ID NO:96, classified in class 530, subclass 387.1+.
- XXIV. Claims 1, 2, 41 and 44 in part and 27, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:98 and the light chain amino acid having a sequence of SEQ ID NO:100, classified in class 530, subclass 387.1+.
- XXV. Claims 1, 2, 41 and 44 in part and 28, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:102 and the light chain amino acid having a sequence of SEQ ID NO:104, classified in class 530, subclass 387.1+.
- XXVI. Claims 1, 2, 41 and 44 in part and 29, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ

ID NO:106 and the light chain amino acid having a sequence of SEQ ID NO:108, classified in class 530, subclass 387.1+.

XXVII. Claims 1, 2, 41 and 44 in part and 30, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:110 and the light chain amino acid having a sequence of SEQ ID NO:112, classified in class 530, subclass 387.1+.

XXVIII. Claims 1, 2, 41 and 44 in part and 31, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:114 and the light chain amino acid having a sequence of SEQ ID NO:116, classified in class 530, subclass 387.1+.

XXIX. Claims 1, 2, 41 and 44 in part and 32, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:116 and the light chain amino acid having a sequence of SEQ ID NO:118, classified in class 530, subclass 387.1+.

XXX. Claims 1, 2, 41 and 44 in part and 33, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:118 and the light chain amino acid having a sequence of SEQ ID NO:120, classified in class 530, subclass 387.1+.

XXXI. Claims 1, 2, 41 and 44 in part and 34, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:122 and the light chain amino acid having a sequence of SEQ ID NO:124, classified in class 530, subclass 387.1+.

XXXII. Claims 1, 2, 41 and 44 in part and 35, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:126 and the light chain amino acid having a sequence of SEQ ID NO:128, classified in class 530, subclass 387.1+.

XXXIII. Claims 1, 2, 41 and 44 in part and 36, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:130 and the light chain amino acid having a sequence of SEQ ID NO:132, classified in class 530, subclass 387.1+.

XXXIV. Claims 1, 2, 41 and 44 in part and 37, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:134 and the light chain amino acid having a sequence of SEQ ID NO:136, classified in class 530, subclass 387.1+.

XXXV. Claims 1, 2, 41 and 44 in part and 38, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:138 and the light chain amino acid having a sequence of SEQ ID NO:140, classified in class 530, subclass 387.1+.

XXXVI. Claims 1, 2, 41 and 44 in part and 39, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a sequence of SEQ ID NO:142 and the light chain amino acid having a sequence of SEQ ID NO:144, classified in class 530, subclass 387.1+.

XXXVII. Claims 1, 2, 41 and 44 in part and 39, drawn to a human monoclonal antibody comprising a heavy chain amino acid having a

sequence of SEQ ID NO:146 and the light chain amino acid having a sequence of SEQ ID NO:148, classified in class 530, subclass 387.1+.

XXXVIII. Claims 42 and 43, drawn to a method of assaying the level of monocyte chemo-attractant protein-1 (MCP-1), classified in class 435, subclass 7.1.

XXXIX. Claims 45 and 46, drawn to a method of effectively treating a neoplastic disease, classified in class 514, subclass 2.

XXXX. Claims 47 and 48, drawn to a method of effectively treating inflammatory conditions, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-XXXVII represent separate and distinct antibody products because they bind to chemically distinct epitopes on a variety of distinct polypeptides that differ in amino acid sequence. Further, the search for antibodies that consist of different sequences and may potentially bind to different antigens, including the portions, and percentages of different amino acid segments would invoke a high search burden. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of four different polypeptides, and different polypeptide segments in the databases would require extensive searching and review. Furthermore, because these inventions are distinct for the reasons given above and the search required for one

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group is not required for another group, restriction for examination purposes as indicated is proper.

The inventions of Groups XXXVIII-XXXX are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case Group XXXVIII recites a method of assaying the level of monocyte chemo-attractant protein-1 (MCP-1), Group XXXIX recites a method of effectively treating a neoplastic disease and Group XXXX recites a method of effectively treating inflammatory conditions. The method of assaying the level of monocyte chemo-attractant protein-1 (MCP-1) differs from that of treating a neoplastic disease, which in turn differs from the method of treating inflammatory conditions. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions XXXVIII-XXXX are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group I-XXXVII and the method of Groups XXXVIII-XXXX are related as product and process of use. The inventions can be shown to be distinct if

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either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography in addition to the materially different methods of Groups XXXVIII-XXXX.

Election of species within Group XXXIX

3. This application contains claims directed to the following patentably distinct species of the claimed invention XXXIX

If group XXXIX is elected, the applicant is required to elect one species from the following list:

- Species a) breast
- Species b) ovarian
- Species c) bladder
- Species d) lung
- Species e) glioblastoma
- Species f) stomach
- Species g) endometrial
- Species h) kidney
- Species i) colon
- Species j) pancreatic

Species k) prostate

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 45 is generic.

The species discussed above patentably distinct because of their distinct properties including the differences in their pathobiologies and modes of administration.

Election of species within Group XXXX

4. This application contains claims directed to the following patentably distinct species of the claimed invention XXXX

If group XXXX is elected, the applicant is required to elect one species from the following list:

Species a) rheumatoid arthritis

Species b) glomerulonephritis

Species c) atherosclerosis

Species d) psoriasis

Species e) restenosis

Species f) autoimmune disease

Species g) multiple sclerosis

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 47 is generic.

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The species discussed above patentably distinct because of their distinct properties including the differences in their pathobiologies and modes of administration.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction

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for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

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"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER